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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/408,905	09/29/99	WALSH	K S1237/7011/E

HM22/1201

ELIZABETH R PLUMER  
WOLF GREENFIELD & SACKS P C  
FEDERAL RESERVE PLAZA  
600 ATLANTIC AVENUE  
BOSTON MA 02210

EXAMINER

NICKOL, G

ART UNIT	PAPER NUMBER
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1642

13

DATE MAILED:

12/01/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

**Office Action Summary**

Application No.

09/408,905

Applicant(s)

WALSH, KENNETH

Examiner

Gary B. Nickol Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 October 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 6-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

The Election filed October 4, 2000 (Paper No. 12) in response to the Office Action of August 30, 2000 is acknowledged and has been entered. Claims 1-38 are pending in the application and Claims 6-38 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions. Claims 1-5 are currently under prosecution

Applicant's election with traverse of Group I, claims 1-5 in Paper No 12 is acknowledged. The traversal is on the ground(s) that the inventions have not been shown to be materially distinct and the inclusion of Groups II and III would not impose a serious burden on the examiner. This is not found persuasive. MPEP 802.01 provides that restriction is proper between inventions which are independent or distinct. Here, the inventions of the various groups are distinct for the reasons set forth in Paper No. 12. Applicant further argues that the inclusion of additional elements in the claims of Groups II and III does not affect the nature of the search that must be conducted. This argument has been considered but is not found persuasive. The literature search, particularly relevant in this art, is not coextensive and is not necessarily the only issue regarding the burden of search. Different searches and issues are involved in the examination of each group. For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

### *Information Disclosure Statement*

The information disclosure statement filed 6-23-00 in Paper No. 8 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It is noted that neither the "modified" PTO-1449 nor the International Search Report in PCT/US99/22633 was included in the communication entered on 6-23-00.

### *Specification*

The specification on page 1 should be amended to reflect the priority status of the present application, for example:

This application claims benefit to provisional application 60/102740, filed October 2, 1998, now abandoned.

The Figures Description on page 6 is objected to because the description of Figure 2 does not include a description of Figure 2A or 2B or 2C. Further, the description of Figure 3B is unclear because it cannot be determined which data group corresponds to which set of points on the graph (or the legend on the graph is unclear.) . Corrections are required.

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cuevas et al. (Eur.J.Med.Res, Vol. 2, pages 465-468, November, 1997) in view of Datta et al. (Cell, Vol. 91, pages 231-241, October, 1997).

The claims are drawn to a method for treating myocardial infarction comprising administering to a subject in need of such treatment an Akt molecule in an amount effective to inhibit cardiac tissue necrosis (Claim 1); wherein the cardiac tissue necrosis is mediated by increased apoptotic cell-death of a cardiomyocyte (Claim 2); wherein the cardiac tissue necrosis is mediated by increased apoptotic cell-death of a cardiac tissue endothelial cell (Claim 3); wherein the Akt molecule is administered acutely (Claim 4).

1. Cuevas et al. teach a method for treating myocardial infarction comprising administering to a subject in need of such treatment a molecule in an amount effective to inhibit cardiac tissue necrosis (abstract) wherein the cardiac tissue necrosis is mediated by increased apoptotic cell-death of a cardiomyocyte (introduction and page 466, 1<sup>st</sup> column) and a cardiac tissue endothelial cell (Fig. 1, page 467) wherein the molecule is also administered acutely (abstract).

2. Cuevas et al. do not include an Akt molecule in the treatment protocol.
3. Datta et al. teach that the Akt molecule is an inhibitor of apoptosis in a variety of cell types (page 231, 2<sup>nd</sup> column, 2<sup>nd</sup> full paragraph).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to substitute the apoptotic inhibitor used by Cuevas et al. with the Akt molecule taught by Datta et al. in order to treat a myocardial infarction because both molecules are well-known in the art to function as inhibitors of apoptosis. Thus, based on the teachings of Datta et al. it would be expected that an Akt molecule would also treat a myocardial infarction. Further, one would have been motivated to do so because Cuevas et al. successfully teach that when FGF was given as a systemic bolus immediately after myocardial ischemia, apoptosis was significantly reduced by 60%. Clearly, since both molecules function to inhibit apoptosis, it would have been obvious to one of ordinary skill in the art to use an Akt molecule to treat myocardial infarctions.

### *Claim Objections*

Claim 5 is objected to as being dependent upon a rejected base claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

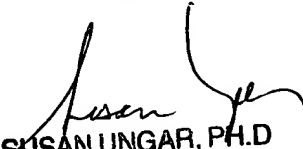
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.  
Examiner  
Art Unit 1642

GBN  
November 30, 2000

  
**SUSAN UNGAR, PH.D.**  
**PRIMARY EXAMINER**